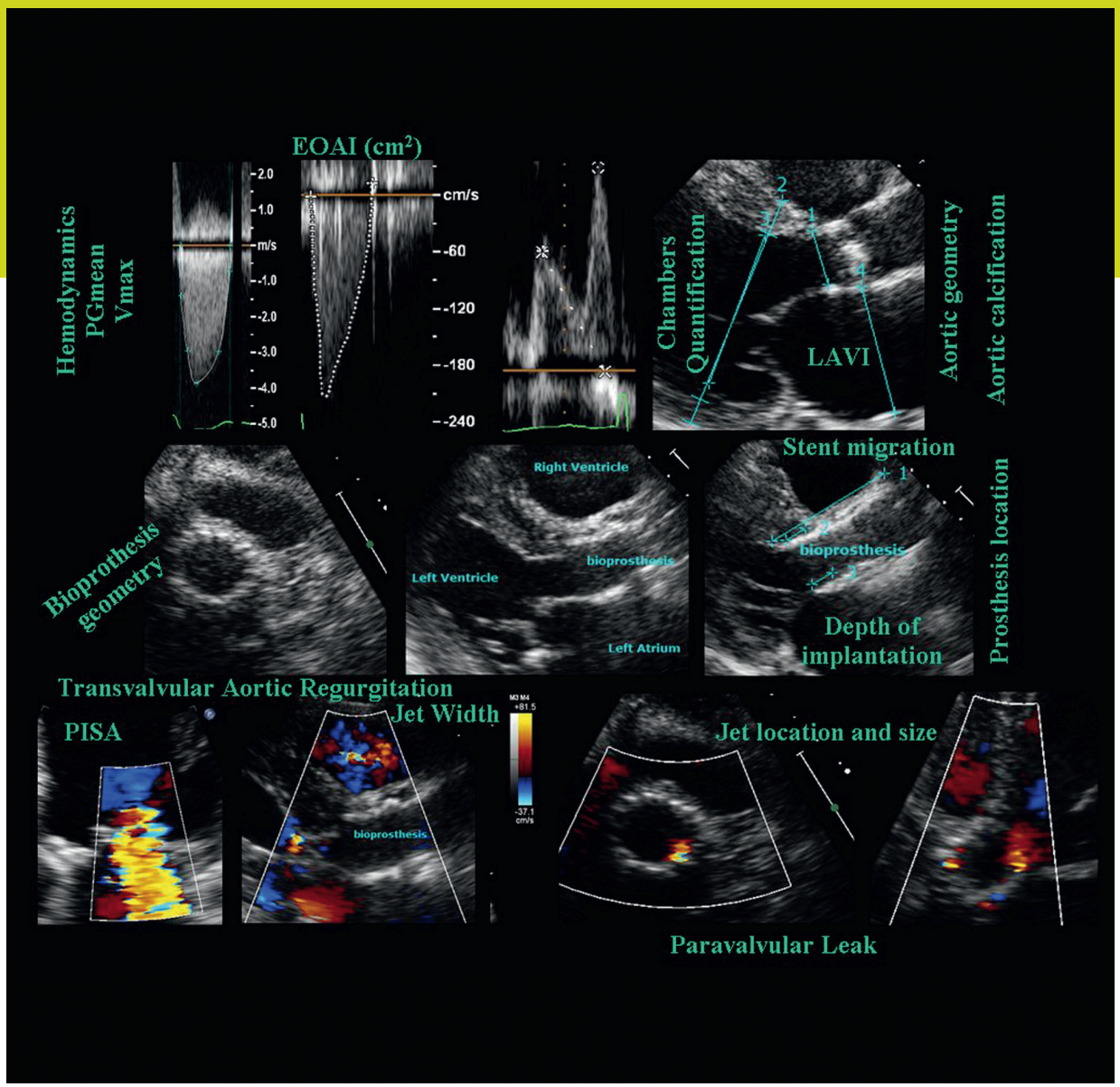
Cardialysis Imaging Core Lab in TAVI Clinical Trials

Cardialysis is an innovative leader in the field of image analysis. Continually researching new and emerging imaging modalities. Such an approach ensures that the evaluation of a novel device/drug will be carried out using cutting edge technology to maximise the information gained from a clinical study. Closely guided by clinical experts in the specific field, Cardialysis serves as a Core Laboratory for a variety of these imaging techniques.



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Transcatheter valve therapies

Introduction

Recent innovations in transcatheter valve therapies have accelerated the development of novel products in this area. At the same time, the lack of peri-procedural structural visualisation of the heart has put multi-modality cardiac imaging supporting the procedure into the spotlight. However, there are several unresolved safety issues, including post-procedural paravalvular leak, atrioventricular heart block, vascular complications, and stroke.

Multi-modality cardiac imaging might help to overcome these safety concerns by minimising TAVI complications. Therefore, imaging is considered a regulatory and clinical necessity during clinical trials involving transcatheter device implantation.

Pre-procedure imaging: before device implantation, imaging is needed for proper planning of prosthesis implantation by selection of the suitable patient, selection of the appropriate prosthesis size, and selection of most beneficial procedural approach (e.g. transfemoral or transapical). This is achieved by confirmation of aortic stenosis severity, evaluation of the aorta and surrounding structures and assessment of the ilio-femoral arterial system.

Post-implantation imaging helps to assess the immediate and long-term procedural results. Procedural success is defined as acceptable valve performance and absent local and general complications such as paravalvular leak and stroke. Several imaging modalities including angiography, echocardiography (transthoracic and transoesophageal), multislice computed tomography (MSCT), and magnetic resonance imaging (MRI) have shown tremendous benefits in TAVI patients.

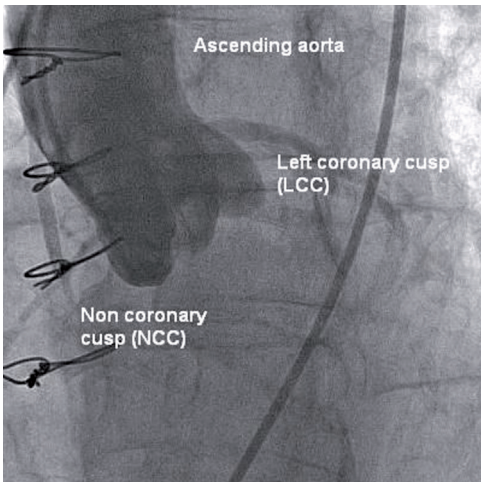
Core Laboratory

The Cardialysis Core Laboratory is fully geared to facilitate the industry in this area of exciting multi-modality transcatheter valve trials, living up to its reputation of innovative partner for the medical device industry.

Under the guidance of the supervising cardiologists Dr. C. Schultz, Dr. N. van Mieghem, Dr. R.-J. van Geuns and Dr. O. Soliman, Cardialysis validated and implemented the golden standard pallet of modalities 'Angiography, MSCT, MRI and echocardiography' according to the latest guidelines for valve assessments.

Valve Academic Research Consortium (VARC)

Cardialysis has a leading role in the Academic Research Consortium (ARC) initiatives. By joining forces with HCRI, DCRI and CRF, and through cooperation with the FDA and relevant clinical societies, the ARC strives to improve clinical research in interventional cardiology and related fields by collaboration, standardisation of clinical trial methodology and harmonisation of endpoints. The objective of the VARC is: to propose standardised consensus definitions for important clinical endpoints in Transcatheter Aortic Valve Implantation (TAVI) investigations in an effort to improve the quality of clinical research and to enable meaningful comparisons between clinical trials and to make these consensus definitions accessible to all stakeholders in TAVI clinical research through a peer reviewed publication, in the interest of public health. The first VARC consensus was published in January 2011. Currently, the consortium is preparing a second consensus publication (VARC-2) in which the selection and some of the definitions are re-examined. In addition, VARC-2 is intended to expand understanding of patient risk stratification and case selection.



Key publications in the field of TAVI from Cardialysis' Core Lab

Standardized endpoint definitions for transcatheter aortic valve implantation clinical trials: a consensus report from the Valve Academic Research Consortium.
Leon MB, Piazza N, Nikolsky E, Blackstone EH, Cutlip DE, Kappetein AP, Krucoff MW, Mack M, Mehran R, Miller C, Morel MA, Petersen J, Popma JJ, Takkenberg JJ, Vahanian A, van Es GA, Vranckx P, Webb JG, Windecker S, Serruys PW. Eur Heart J. 2011 Jan;32(2):205-17. Epub 2011 Jan 6.

Assessment of the aortic annulus by multislice computed tomography, contrast aortography, and trans-thoracic echocardiography in patients referred for transcatheter aortic valve implantation.
Tzikas A, Schultz CJ, Piazza N, Moelker A, Van Mieghem NM, Nuis RJ, van Geuns RJ, Geleijnse ML, Serruys PW, de Jaegere PP. Catheter Cardiovasc Interv. 2011 May 1;77(6):868-75. doi: 10.1002/ccd.22761. Epub 2011 Apr 14.

ECG

Timing and potential mechanisms of new conduction abnormalities during the implantation of the Medtronic CoreValve System in patients with aortic stenosis.
Nuis RJ, Van Mieghem NM, Schultz CJ, Tzikas A, Van der Boon RM, Maugenest AM, Cheng J, Piazza N, van Domburg RT, Serruys PW, de Jaegere PP. Eur Heart J. 2011 Aug;32(16):2067-74. Epub 2011 May 28.

Angiography

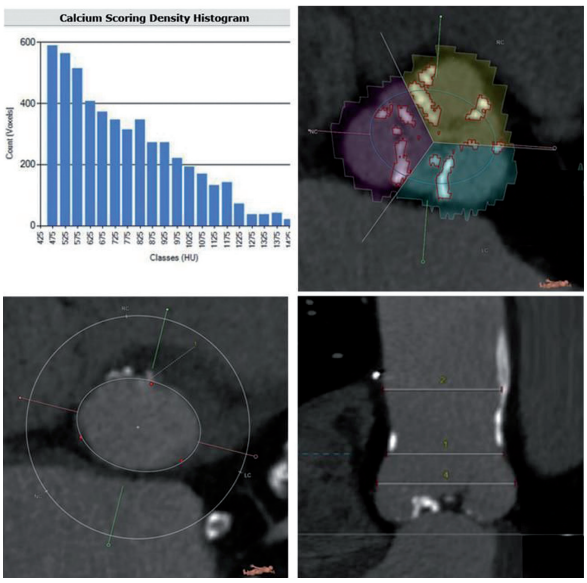
A clinical protocol for analysis of the structural integrity of the Medtronic CoreValve System® frame and its application in patients with 1-year minimum follow-up.
Piazza N, Grube E, Gerckens U, Schuler G, Linke A, den Heijer P, Kovacs J, Spyt T, Laborde JC, Morel MA, Nuis RJ, Garcia-Garcia HM, de Jaegere P, Serruys PW. EuroIntervention 2010 Jan;5(6):680-6

Optimal projection estimation for transcatheter aortic valve implantation based on contrast-angiography: validation of a prototype software.
Tzikas A, Schultz C, Van Mieghem NM, De Jaegere PP, Serruys PW. Catheter Cardiovascular Interventions 2010; 4: 602-607.

MSCT

Geometry and degree of apposition of the CoreValve ReValving system with multislice computed tomography after implantation in patients with aortic stenosis.
Schultz CJ, Weustink A, Piazza N, Otten A, Mollet N, Krestin G, van Geuns RJ, de Feyter P, Serruys PW, de Jaegere P. J Am Coll Cardiol. 2009 Sep 1;54(10):911-8.

The use of MSCT for the evaluation of the aortic root before transcutaneous aortic valve implantation: the Rotterdam approach.
Schultz C, Moelker A, Tzikas A, Piazza N, de Feyter P, van Geuns RJ, Serruys PW, Krestin GP, de Jaegere P. EuroIntervention. 2010 Sep;6(4):505-11. doi: 10.4244/EIJ30V6I4A84.



ECHO

Early echocardiographic evaluation following percutaneous implantation with the self-expanding CoreValve Revalving System aortic valve bioprosthesis.
De Jaegere PP, Piazza N, Galema TW, Otten A, Soliman OI, Van Dalen BM, Geleijnse ML, Kappetein AP, Garcia HM, Van Es GA, Serruys PW. EuroIntervention. 2008 Nov;4(3):351-7.

Changes in mitral regurgitation after transcatheter aortic valve implantation.
Tzikas A, Piazza N, van Dalen BM, Schultz C, Geleijnse ML, van Geuns RJ, Galema TW, Nuis RJ, Otten A, Gutierrez-Chico JL, Serruys PW, de Jaegere PP. Catheter Cardiovasc Interv. 2010 Jan 1;75(1):43-9.

Left ventricular mass regression one year after transcatheter aortic valve implantation.
Tzikas A, Geleijnse ML, Van Mieghem NM, Schultz CJ, Nuis RJ, van Dalen BM, Sarno G, van Domburg RT, Serruys PW, de Jaegere PP. Ann Thorac Surg. 2011 Mar;91(3):685-91.

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About Cardialysis

Cardialysis is an independent clinical Contract Research Organisation (CRO) offering high quality services in the field of cardiology with its focus on Interventional Cardiology, both Devices and Pharmacological Treatments, and Electrophysiology. Cardialysis is recognised for its opinion-leader expertise, strong academic network, statistical expertise, innovative core laboratory technologies and imaging techniques, event adjudication and professional execution of clinical trials.

Based in Rotterdam, the Netherlands, Cardialysis has been facilitating clinical trials for medical devices and pharmaceutical products since 1983 and gained ample experience in phase II (Proof of Concept), phase III and CE-mark clinical trials. All processes are in compliance with Good Clinical Practice (GCP) and with the guidelines of the European Medicines Agency (EMA), the Food and Drug Administration (FDA) and the International Conference on Harmonisation (ICH).

Furthermore, Cardialysis offers a complete package of services, from protocol design to data management and reporting for clinical trials in cardiology.

Cardialysis concentrates its activities on the following areas:

- Trial Design
- Project Management
- Site Selection
- Clinical Monitoring
- Safety Monitoring & Reporting
- Data Management
- Statistical Analysis
- Event Adjudication Services
- Core Laboratory

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